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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,012	09/06/2000	Jeffrey Owen Phillips	CUMP.75681	7874

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EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 12/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/600,012	PHILLIPS ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-19,21-29 and 31-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-19,21-29 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 10-11, 14, 16-17, 19, 21, 24, 26, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,117,836 to Millar in view of U.S. Patent 5,833,603 to Kovacs et al., and further in view of U.S. Patent 4,904,237 to Janese. Millar discloses a method and apparatus for implanting a ventricular catheter having one end residing in the ventricular region and the other end exiting the cranial region at a distal location. (Abstract of Millar). Millar discloses an opening in the skull 14 and the insertion of the catheter 26 into a region of cerebral spinal fluid 22. (Fig. 1 of Millar). The catheter 26 has openings 28 which allow intracranial fluid to pass from brain 20 to the inside of the catheter. (column 6, lines 9-18 of Millar). A transducer 40 is placed in catheter 26. (column 6, lines 19-41 of Millar). The transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Millar does not explicitly teach the use of a pH sensor inside the body. Millar teaches that the transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Kovacs et

al. teaches a pH sensor (column 3, lines 34-36 of Kovacs et al.) that is inserted into cerebrospinal fluid (column 10, lines 19-23 of Kovacs et al.) which can be placed on a flexible catheter (column 5, lines 35-38 of Kovacs et al.). Such a sensor falls within the scope of chemical content as suggested by Millar et al. since pH is a measure of hydrogen-ion concentration. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pH sensor of Kovacs et al. in the method and apparatus of Millar et al. since Millar et al. teaches that sensors that measure chemical content can be used and Kovacs et al. teaches one such sensor. The combination does not teach the monitoring of the CSF fluid within the initial 24 hours following trauma. It is known in the art that diagnosis, management, and/or treatments of cerebral spinal fluid takes place during intra-cranial arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage. (column 10, lines 23-35 of Janese). The purpose of the invention is to function as a diagnostic tool at such times. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the combination at times of arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage since it is the purpose of the combination to provide diagnostic aid at these times. The combination does not disclose monitoring within the initial 24 or 48 hours of the trauma. It is known in the art that the monitoring and treatment of patients after a trauma is routinely performed to improve the patient's chances for survival. The patient's survival will particularly increase if monitoring and treatment are initiated as soon possible after the trauma.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of the combination to include initiating monitoring and treatment within 24 hours from the head trauma since the immediate attention will improve the patient's chances for survival. In regard to claim 11, the catheter is implanted in the ventricular region. (Abstract of Millar). In regard to claims 14 and 24, the sensor includes an extension tube 14 and the sensor is locked within the catheter by the use of a seal 56. (Fig. 5 of Millar). In regard to claims 16, and 26, Millar teaches that the transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Kovacs et al. teaches a sensor for determining CO_2 and O_2 (column 10, lines 3-17 of Kovacs et al.) that is inserted into cerebrospinal fluid (column 10, lines 19-23 of Kovacs et al.) which can be placed on a flexible catheter (column 5, lines 35-38 of Kovacs et al.). Such a sensor falls within the scope of chemical content as suggested by Millar et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the CO_2 and O_2 sensors of Kovacs et al. in the method and apparatus of the combination since Millar et al. teaches that sensors that measure chemical content can be used and Kovacs et al. teaches one such sensor. In regard to claim 17 and 27, Janese teaches that the pH and other parameters are monitored to detect any dangerous or significant changes in the medical management of the patient. These changes alert the technician that something is wrong with the system or the patient which requires immediate attention. (column 8, lines 50-60 of Janese). The arrangement inherently includes comparing the reading with a base line

or threshold. Therefore, it would have been obvious to compare the pH with a baseline since changes relative to the baseline can alert the technician that something is wrong with the patient which requires immediate attention.

3. Claims 13 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,117,836 to Millar in view of U.S. Patent 5,833,603 to Kovacs et al., and further in view of U.S. Patent 4,904,237 to Janese as applied to claims 10 and 21, and further in view in view of U.S. Patent 5,830,188 to Abouleish. The combination does not teach inserting the catheter into a region of cerebral spinal fluid until expression of the fluid indicate that the catheter has reached the cerebral ventricle. It is well known in the art that expression of cerebral spinal fluid is an indication that the catheter is properly inserted in a region of cerebral spinal fluid. (column 5, lines 25-33 of Abouleish). Such a method provides the necessary information for the caregiver to carry out the insertion step as required by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use expression of the cerebral spinal fluid to indicate that the catheter is properly positioned since such a method provides the necessary information for the caregiver to carry out the insertion step as required by the combination.

4. Claims 10-12, 15, 21-22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. in view of U.S. Patent 4,903,707 to Knute et al., and further in view of U.S. Patent 4,904,237 to Janese.

Kovacs et al. teaches a pH sensor (column 3, lines 34-36 of Kovacs et al.) that is inserted into cerebrospinal fluid (column 10, lines 19-23 of Kovacs et al.) which can be placed on a flexible catheter (column 5, lines 35-38 of Kovacs et al.). Kovacs et al. does not teach a specific embodiment of the catheter for examination in cerebrospinal fluid. Knute et al. teaches a catheter assembly for examination in cerebrospinal fluid. Such a catheter assembly would fall within the scope of the catheter suggested by Kovacs et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to mount the sensor of Kovacs et al. on the catheter of Knute et al. since Kovacs et al. teaches that the sensor can be mounted on a catheter and Knute et al. teaches one such catheter. In regard to claim 10, the catheter assembly is inserted through an opening in a skull to monitor a parameter of the brain. (column 1, lines 42-45 of Knute et al.). The combination does not teach the monitoring of the CSF fluid within the initial 24 hours following trauma. It is known in the art that diagnosis, management, and/or treatments of cerebral spinal fluid takes place during intra-cranial arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage. (column 10, lines 23-35 of Janese). The purpose of the invention is to function as a diagnostic tool at such times. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the combination at times of arterial vasospasm, subarachnoid hemorrhage, trauma to the brain and spinal cord, and fetal intra-cranial hemorrhage since it is the purpose of the combination to provide diagnostic aid at these times. The combination does not disclose monitoring within the initial 24 or 48 hours of

the trauma. It is known in the art that the monitoring and treatment of patients after a trauma is routinely performed to improve the patient's chances for survival. The patient's survival will particularly increase if monitoring and treatment are initiated as soon possible after the trauma. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus of the combination to include initiating monitoring and treatment within 24 hours from the head trauma since the immediate attention will improve the patient's chances for survival. In regard to claims 10 and 21, a hole is drilled in the skull, a catheter is inserted into a CSF region, and changes of the pH are measured. (Fig. 1 of Knute et al.).

5. Claims 18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. in view of U.S. Patent 4,903,707 to Knute et al. and further in view of U.S. Patent 4,904,237 to Janese as applied to claims 10, 21, 31, and 36, and further in view of U.S. Patents 5,403,746 to Bentsen et al. and Re. 31,879 to Lubbers et al. The combination does not teach collecting, storing, and comparing the pH data. The combination teaches many techniques for using organic and inorganic dyes can be used. (column 10, lines 3-17 of Kovacs et al.). It is well known in the art that techniques and the apparatuses for carrying out the techniques include processors for processing signals from chemical dye sensors which collect, store and compare readings. (column 20, lines 50-67 of Bentsen et al. which incorporates column 6, line 66 to column 7, line 8 of U.S. Patent Reissue Re. 31,879 to

Lubbers et al.). These techniques of processing fall under the scope of techniques suggested by Kovacs et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the processing method and hardware of Bentsen et al. and Lubbers et al. in the combination since Kovacs et al. teaches many techniques of using organic and inorganic dyes can be used and Bentsen et al. and Lubbers et al. teaches such techniques.

6. Claims 31, 34, 36, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,117,836 to Millar in view of U.S. Patent 5,833,603 to Kovacs et al., and further in view of U.S. Patent 6,049,727 to Crothall. Millar discloses a method and apparatus for implanting a ventricular catheter having one end residing in the ventricular region and the other end exiting the cranial region at a distal location. (Abstract of Millar). Millar discloses an opening in the skull 14 and the insertion of the catheter 26 into a region of cerebral spinal fluid 22. (Fig. 1 of Millar). The catheter 26 has openings 28 which allow intracranial fluid to pass from brain 20 to the inside of the catheter. (column 6, lines 9-18 of Millar). A transducer 40 is placed in catheter 26. (column 6, lines 19-41 of Millar). The transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Millar does not explicitly teach the use of a pH sensor inside the body. Millar teaches that the transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Kovacs et al. teaches a pH sensor (column 3, lines 34-36 of Kovacs et al.) that is inserted into cerebrospinal fluid

(column 10, lines 19-23 of Kovacs et al.) which can be placed on a flexible catheter (column 5, lines 35-38 of Kovacs et al.). Such a sensor falls within the scope of chemical content as suggested by Millar et al. since pH is a measure of hydrogen-ion concentration. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the pH sensor of Kovacs et al. in the method and apparatus of Millar et al. since Millar et al. teaches that sensors that measure chemical content can be used and Kovacs et al. teaches one such sensor. The combination does not teach a porous sheath. Crothall teaches the use of a porous sheath that is used to protect the sensor from troublesome tissue and debris. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a porous sheath as disclosed by Crothall since a porous sheath would protect the sensor from troublesome tissue and debris. In regard to claims 34 and 39, Millar teaches that the transducer is used to measure chemical content, pressure, hemodynamics, and waveform responses. (column 4, lines 28-32 of Millar). Kovacs et al. teaches a sensor for determining CO_2 and O_2 (column 10, lines 3-17 of Kovacs et al.) that is inserted into cerebrospinal fluid (column 10, lines 19-23 of Kovacs et al.) which can be placed on a flexible catheter (column 5, lines 35-38 of Kovacs et al.). Such a sensor falls within the scope of chemical content as suggested by Millar et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the CO_2 and O_2 sensors of Kovacs et al. in the method and apparatus of the combination since Millar et al. teaches that sensors that measure chemical content can be used and Kovacs et al. teaches one such sensor.

7. Claims 31-33 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. in view of U.S. Patent 4,903,707 to Knute et al., and further in view of U.S. Patent 6,049,727 to Crothall. Kovacs et al. teaches a pH sensor (column 3, lines 34-36 of Kovacs et al.) that is inserted into cerebrospinal fluid (column 10, lines 19-23 of Kovacs et al.) which can be placed on a flexible catheter (column 5, lines 35-38 of Kovacs et al.). Kovacs et al. does not teach a specific embodiment of the catheter for examination in cerebrospinal fluid. Knute et al. teaches a catheter assembly for examination in cerebrospinal fluid. Such a catheter assembly would fall within the scope of the catheter suggested by Kovacs et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to mount the sensor of Kovacs et al. on the catheter of Knute et al. since Kovacs et al. teaches that the sensor can be mounted on a catheter and Knute et al. teaches one such catheter. The combination does not teach a porous sheath. Crothall teaches the use of a porous sheath that is used to protect the sensor from troublesome tissue and debris. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a porous sheath as disclosed by Crothall since a porous sheath would protect the sensor from troublesome tissue and debris. In regard to claims 31-32 and 36-37, the catheter 21 includes a rigid portion 33 adapted to fit slidingly within the opening 29 in the bolt means 17 and a flexible portion 35 adapted to penetrate into a ventricle 37 of the brain. The flexible portion 35 has an opening 39 from the lumen 31 to an exterior surface 41 of the

catheter 19 for communication between the lumen 31 and any fluid 43 (including cerebrospinal fluid) adjacent the catheter 19. (column 3, lines 22-39 of Knute et al.). In regard to claims 33 and 38, there are means for draining fluid from the brain and a pressure transducer. (column 4, lines 9-20 of Knute et al.).

8. Claims 35 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,833,603 to Kovacs et al. in view of U.S. Patent 4,903,707 to Knute et al., and further in view of U.S. Patent 6,049,727 to Crothall as applied to claims 31 and 36, and further in view of U.S. Patents 5,403,746 to Bentsen et al. and Re. 31,879 to Lubbers et al. The combination does not teach collecting, storing, and comparing the pH data. The combination teaches many techniques for using organic and inorganic dyes can be used. (column 10, lines 3-17 of Kovacs et al.). It is well known in the art that techniques and the apparatuses for carrying out the techniques include processors for processing signals from chemical dye sensors which collect, store and compare readings. (column 20, lines 50-67 of Bentsen et al. which incorporates column 6, line 66 to column 7, line 8 of U.S. Patent Reissue Re. 31,879 to Lubbers et al.). These techniques of processing fall under the scope of techniques suggested by Kovacs et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the processing method and hardware of Bentsen et al. and Lubbers et al. in the combination since Kovacs et al. teaches many techniques of using organic and inorganic dyes can be used and Bentsen et al. and Lubbers et al. teaches such techniques.

Response to Arguments

9. Applicant's arguments filed 9/25/2003 have been fully considered but they are not persuasive. The Applicant contends that the one with ordinary skill in the art would not use the Millar/Kovacs/Janese combination within 24 or 48 hours following a head trauma. The Examiner is respectfully disagrees. In the area of medical diagnosis and treatment, the doctors are to evaluate a patient on a case-by-case basis. When a patient suffers a serious head injury, they are placed under observation for 48 hours. (Offbeat Outline News at http://www.info.gov.hk/police/offbeat/archives/644/news3.html). One with ordinary skill in the art would recognize that if any problems occur within the 48 hour window, action by a doctor would occur. Further, it is suggested that for head injuries diagnosis and treatment should take place as soon as possible after the injury. (column 6, lines 44-55 of U.S. Patent 5,531,776 to Ward et al.). Indeed, it has been suggested that the doctor may be able to determine is serious cases within an hour or two. (column 1, lines 10-20 of U.S. Patent 5,951,476 to Beach and column 8, lines 12-16 of Ward et al.). From these teaches, it is established that the monitoring and treatment of patients after a trauma is routinely performed to improve the patient's chances for survival. The patient's survival will particularly increase if monitoring and treatment are initiated as soon possible after the trauma and such determination may take place within 48 hours and even within 2 hours of the injury. Janese teaches the type of actions that a

physician that a doctor would take in view of any problems that would occur within the 48 hours and the combination teaches such actions. Therefore, the idea of using the method of the combination within 48 hours from a head injury is not non-obvious. In regards to Applicant's argument that the combination does not teach that monitoring pH would have diagnostic value, the Examiner respectfully disagrees since Janese teaches that the monitoring of pH in the CSF fluid has significance and is desired to be within a specific range. (column 7, lines 5-31of Janese).

10. Applicant's arguments with respect to claims 31-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
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